Response and Amendment under 37 CFR § 1.111 Application No. 09/899,026

Duclos teaches a solid dispersion of fenofibrate in polyvinylpyrrolidone that is prepared by dissolving the fenofibrate and polyvinylpyrrolidone in an organic solvent, evaporating the organic solvent, and coprecipitating the fenofibrate and polyvinylpyrrolidone as a solid dispersion (Duclos at column 3, lines 1-20 and columns 16-18).

One skilled in the art would recognize that the dissolution-evaporation-coprecipitation process described by Duclos does not produce the presently claimed micronized fenofibrate having a particle size less than 20 μ m. Moreover, there is no motivation or suggestion to modify the process described in Duclos to produce the presently claimed micronized fenofibrate having a particle size less than 20 μ m.

Second, Duclos does not disclose, suggest or provide motivation to coat the surface of an inert hydrosoluble carrier with an admixture of micronized fenofibrate and a hydrophilic polymer, as in the presently claimed invention.

Duclos teaches that the solid dispersion of fenofibrate and polyvinylpyrrolidone (i.e., pulverulent product) may be coated with a carrier or pharmaceutical vehicle using a fluidized bed granulation technique (Duclos at column 6, lines 17-26). Thus, Duclos teaches away from the claimed invention. In Duclos, the carrier coats the solid dispersion of fenofibrate and polyvinylpyrrolidone. In the claimed invention, the admixture of micronized fenofibrate and hydrophilic polymer coats the inert hydrosoluble carrier.

Duclos does not disclose, suggest or provide motivation to coat the inert carrier or pharmaceutical vehicle with the solid dispersion of fenofibrate and polyvinylpyrrolidone (e.g., the pulverulent product). One skilled in the art would recognize that process described in Duclos does not produce the presently claimed inert particles that are coated with the admixture of micronized fenofibrate and a hydrophilic polymer. Moreover, there is no motivation or suggestion to modify the process in Duclos to arrive at the claimed invention.

Again, Duclos does not disclose, suggest or provide motivation to use micronized fenofibrate, and Duclos does not disclose, suggest or provide motivation to coat the surface of inert hydrosoluble carriers with an admixture of fenofibrate and a hydrophilic polymer.

Response and Amendment under 37 CFR § 1.111 Application No. 09/899,026

In view of the above, Applicants respectfully submit that the presently claimed invention is not anticipated by and is unobvious over the cited reference, and respectfully request that the rejection under 35 USC § 102 be withdrawn.

V. Conclusion

An early and favorable reconsideration and allowance of claims 35-90 is respectfully requested.

Respectfully submitted,

Edward D. Grieff

Registration No. 38,898

Date: January 22, 2002

Hale and Dorr LLP 1455 Pennsylvania Avenue, NW Washington, DC 20004

Phone: 202-942-8453